

REMARKS

Claims 1-53 are presently pending in this application and have been subject to restriction as follows:

I. Claims 1-18 are drawn to nucleic acid molecules comprising, for example, two or more target binding domains and a 3' splice region comprising a branch point, a pyrimidine tract and a 3' splice acceptor site and a 5' splice donor site, vectors, compositions and cells comprising a nucleic acid molecule, classified in class 435, subclass 325;

II. Claims 19-25 drawn to a method of producing a chimeric RNA molecule in a cell, classified in class 435, and subclass 6;

III. Claims 26-44 and 52 drawn to nucleic acid molecules comprising, for example, one or more target binding domains and a 5' splice donor site, vectors, compositions and cells comprising a nucleic acid molecule, classified in class 435, subclass 325;

IV. Claims 45-51 drawn to a method of producing chimeric RNA molecule in a cell, classified in class 435 and subclass 6;

V. Claim 53 drawn to a nucleic acid molecule wherein said nucleic acid molecule is CFTR PTM24, classified in class 536, subclass 23.1

In support of the present restriction requirement, the Examiner has alleged that the subject matter of the pending claims represent distinct inventions.

In particular, the Examiner alleges that Inventions I and II are related as product and process of use. The Examiner further alleges that the Inventions III and IV II are related as product and process of use. According to the Examiner, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner maintains that in the instant case the nucleic acid molecules, vectors and cells recited in invention I and III can be used for a materially different method other than the methods set forth in invention II and IV. For example the nucleic acid molecules of Invention I and III can be used for producing proteins encoded by the *trans*-spliced gene products encoded by the nucleic acid molecules comprised within the respective nucleic acid molecules according to Invention I.

The Examiner concludes that because the inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, Inventions I, III and IV are unrelated since they are drawn to chemically and structurally distinct nucleic acid molecules.

The requirement for restriction is respectfully traversed for a number of reasons. First, there is clearly a structural and functional relationship between the claims of Group I and II. Specifically, the claims of groups I and II directly relate to compositions and methods for targeting *trans*-splicing utilizing pre-*trans*-splicing molecules having two or more target binding domains for the purpose of expressing a chimeric mRNA.

Second, contrary to the Examiner's contention the nucleic acid molecules, vectors and cells of Group I are not designed to be used for the production of proteins encoded by the claimed nucleic acid molecule. In fact, the claimed nucleic acid molecules of Group I have no use independent from their ability to mediate a *trans*-splicing reaction which results in the production of a chimeric RNA molecule (Group II claims). In other words, the process for using

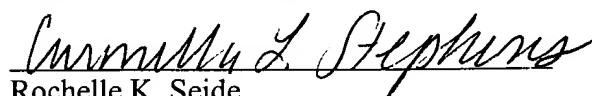
the product as claimed cannot be practiced with another materially different product **and** the product as claimed cannot be used in a materially different process of using that product.

Moreover, Applicant's respectfully direct the Examiner's attention to the claims of U.S. Patent No: 6,280,978 ("the '978 patent"), a patent to which the present application claims priority. The claims are attached herewith as Exhibit A. A review of the claims issued in the '978 patent demonstrates that the Patent and Trademark Office had previously determined that claims to compositions capable of targeting binding to a pre-mRNA and methods for producing a chimeric RNA molecule in a cell utilizing such compositions were considered a single invention.

Finally, given the relationship between the subject matter encompassed by the pending claims of Groups I and II, Applicants assert that there would not be an undue search burden to examine the pending claims as a single group.

However, in order to be fully responsive to the requirement for restriction, Applicants elect, with traverse, the claimed nucleic acid molecules, vectors, compositions and cells of Group I. Withdrawal of the requirement for restriction and favorable consideration and allowance is earnestly solicited.

Respectfully submitted,

  
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